

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**RAJYA SABHA
UNSTARRED QUESTION NO. 3649
TO BE ANSWERED ON 27TH MARCH, 2018**

GUIDELINES FOR SAFE DISPOSAL OF EXPIRED MEDICINES

3649. SHRIMATI RENUKA CHOWDHURY:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) whether Government has formulated any clear guidelines for safe disposal of expired and leftover antibiotics;
- (b) if so, the details thereof and if not, the reasons therefor; and
- (c) the fresh steps taken by Government to check growing anti-microbial resistance due to discharge of drugs and chemicals into environment?

ANSWER

**THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)**

(a) to (c): Good Manufacturing Practices (GMP) and Requirements of Premises, Plant and Equipment for pharmaceutical products laid down in Schedule M of the Drugs and Cosmetics Rules, 1945 prescribe the requirements for disposal of waste including the rejected drugs. Details are as under:

- I. The disposal of sewage and effluents (solid, liquid and gas) from the manufactory shall be in conformity with the requirements of Environment Pollution Control Board.
- II. All bio-medical waste shall be destroyed as per the provisions of the Bio-Medical Waste (Management and Handling) Rules, 1996.
- III. Additional precautions shall be taken for the storage and disposal of rejected drugs. Records shall be maintained for all disposal of waste.
- IV. Provisions shall be made for the proper and safe storage of waste materials awaiting disposal. Hazardous, toxic substances and flammable materials shall be stored in suitably designed and segregated, enclosed areas in conformity with Central and State Legislations.

One of the conditions of drug manufacturing license granted under the Drugs and Cosmetics Rules, 1940 is that the Licensees shall comply with the Good Manufacturing Practices (GMP) requirements prescribed in Schedule M of the said Rules. State Licensing Authorities appointed by the respective State Governments are empowered to take action in case of any violation of above requirements.

The Government has taken various regulatory measures to curb the misuse of antibiotics. However, no report/incidence of growing of anti-microbial resistance of drugs due to discharge of drugs and chemicals into environment has been brought to notice of this Ministry.